BBGuy Essentials 061CE:
Better AABB Assessments with Anne Chenoweth
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Joe: Hi everyone and welcome. This is Blood Bank Guy Essentials, the podcast designed to help you learn the essentials of transfusion medicine. This is episode 061CE and I am Joe Chaffin. You know, today on the podcast, I have an interview that I can only describe as “rollicking, crazy fun" with the AABB's Director of Accreditation and Quality. Her name is Anne Chenoweth. Anne is here to help all of us experience better and more fun AABB assessments.

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I've heard Anne Chenoweth speak on numerous occasions, both in person as well as over webinars and eCasts. Usually when I hear Anne talk, I think something along the lines of, "She is *really* fun. Why does she work for AABB?" (No offense, my AABB friends. Don't get offended). Anne is irreverent, she's funny, and she's also brilliant, which quite frankly is not fair. That's just not fair to the rest of us for her to be all those things at once. I wanted to talk to Anne about how we can get more from our AABB assessments and how that moment when you hear, [FANFARE], "The AABB is here," that can be something that you actually look forward to. Yeah, okay...that might be a little much, but you know what I'm saying. Whether you work at one of the over 1300 or so AABB-accredited facilities around the world or not, you're going to gain some really valuable information and knowledge from this interview that you can use to make your facility better. With that, here is my interview with Anne Chenoweth on better AABB assessments.

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Joe: Well, hey, Anne! Welcome to the Blood Bank Guy Essentials Podcast.

Anne: Thanks so much. I'm really happy to be here and looking forward to having a nice talk.

Joe: Yes. Me too. I have to tell you, your “Senior Director of Accreditation and Quality Department for the AABB” role kind of intimidates me a little bit. I'm a little scared. [laughs]

Anne: [Laughs] Yeah, all five foot two of me. Yeah.

Joe: People that are five foot two have a lot of power…

Anne: That's it.

Joe: …I gotta tell you right now. I say that because my wife is that, so you know...

Anne: Aha. See. You be careful of us little women!

Joe: [Laughs]

Anne: Actually, it's not that significant. AABB, of course, we're best known for accreditation and standards, but we have many facets as you know, our education arm, our publications arm, regulatory and so forth. As the Director of Quality and Accreditation, I oversee the accreditation program for the AABB. Accreditation and standards are always kind of hooked together, but you need to understand that we are two distinct departments in AABB. I work very closely with my counterpart, Christopher Bocquet, the Director of Standards. He oversees that portion and then it bounces to accreditation.

The "quality" in my title is, just as we require all of our facilities who are accredited to follow a quality plan, we do also "walk the talk" at the AABB and I am the quality officer. I make sure that everybody keeps their policies, processes, and procedures and master lists up to date and so forth and do internal audits here within the organization. We try and not ask anything of our facilities that we are not actively doing here in our own association.

Joe: I wonder if you'd take just a few minutes to give us a little bit of a thumbnail about AABB. Where did AABB come from? I know this'll be familiar to a lot of people, but to people that are just starting out, how would you describe what AABB's role is and has been in the blood banking world over the years?

Anne: Absolutely. Okay. We are the patient's advocate for patient and donor safety. That's our whole world. That's what we revolve around. Actually, the AABB began as kind of an idea in 1947 by some blood bank professionals. They were thinking of, "Maybe we should put our heads together and start some kind of association." Very hazy talks at that time. Then, there was a terrible incident in Galveston Bay, the "Grandcamp." It was a French frigate filled with fertilizer. It exploded. If you look at newspapers from that time, it devastated Galveston. Blood started coming

from all over the United States for the victims, and it was noted that everybody labeled things differently. Everybody tested things differently. Everybody did everything in their own way. The same group that was talking about forming an association thought, "You know, not only do we need an association but we need to start standardizing how everybody does things."

And so, the first issue of "Standards for Blood Banks and Transfusion Services" was written in 1957. We started an inspection program at the same time. We've been around for "donkeys years" [*NOTE: If this phrase is as unfamiliar to you as it was me, Anne means, "A really long time!"*] They've evolved over the years. Cellular therapy came to be, and then relationship testing and now molecular and immunohematology Standards. They kept evolving. We were a straight up and down inspection audit program.

In the '90s, the AABB decided that we had taken "inspection" as far as it could go, as far as patient and safety. We needed to leap to the next level. We created the "Quality System Essentials." They're the 10 chapter headings for every Standards. We moved away from an audit inspection to a "quality system assessment." This was a big leap for people. I remember I was a transfusion service manager. I thought, "Oh, I can never do this. This is too much work." Then you realize that you're basically doing these things, you just need the framework. We have been, since that time, doing quality system assessments. This is where everybody always laughs at me because I go all cross-eyed and weird when you start using the word "inspection," because we don't do an inspection. We don't have inspectors or surveyors. We have "assessors" and we do "assessments."

The difference is think of an inspection as using a checklist. You go in and you say to somebody, "Do you have a process to do X?" The answer is either yes or no. You just move on to the next thing. If it's no, you tell them they get a deficiency because they don't have a process, which is okay. They write a process and that's great. With a systems assessment, you'll notice my assessors will say, "Do you have a process for X?" Then you say "yes" and you're like, "Okay, how are people trained in it? How do you know people are following it? What happens if you change it? Where is it documented? Can I see what things happen?" If they're nonconformances or deficiency... You see, it starts mushrooming out into your entire system.

By doing that, we're your PARTNERS in performance improvement. We're not there to show you where your deficiencies are. We're there as another set of eyes to be your partner. We're your peers. You're so close to your system, it's hard for you to see where you might have potential potholes, so we're there to help you to see where you need to improve so that something doesn't happen down the road.

Then, we start bundling nonconformances to show you where you might have an issue. For instance, if I see you've got an old SOP still in the manual, you've got some quality records that are missing information, you have not reviewed some policies, I could write three nonconformances. You'd fix them all and everybody would be happy. What the assessor's going to do is they're going to roll all of these three things up into "document control," because what we want to do is show you the objective evidence we found points us to the idea that you may have a document control issue. By looking at it at a high level of your quality plan of document control, you'll be able to fix things and then you won't have a catastrophic error or issue down the road.

You need to think of the assessment as a partnership, a learning and educational partnership, not us coming in to see where we can "ding you" or us coming in to tell you where you have deficiencies. There are other accreditors that can do that. When we started becoming more global, moving away from ... not away from blood banking, but into all these new areas, we decided that the American Association of Blood Banks was not really a good descriptor. We changed the name to "AABB," kind of like Prince. You know, we want to be cool. We're now AABB. Because we are an incorporated entity, we always have to say "AABB, formerly known as the American Association of Blood Banking." Everyone always is like, "What's your name?" Well, it's ... we're like Cher. That's kind of how the whole American Association of Blood Banks got to be just AABB, formerly known as ...

Joe: That's fantastic. Right. Yes. Well, I ... that may be the quote of this entire episode, no matter what else we say...

Anne: Yeah. That's it [laughs]

Joe: I'm going to hear, "Kind of like Prince." That's the thing that's going to go through my head. That's fantastic. We should just stop now because it's not going to get any better than that! No, I'm kidding. It's going to get better than that. Actually, as I'm listening to you Anne, I'm sitting there ... I'm almost looking forward to my next AABB assessment now...

Anne: You should! [laughs]

Joe: ...because it sounds like so much fun! I mean, honestly, we're blood bankers and we know that it feels like every other day, someone's darkening our door with another...I'm going to say the word, don't get hives..."inspection"...

Anne: Absolutely. Well, we're so highly regulated. We're so highly regulated. There's no other industry that I know of that is so inundated with everybody who's got more initials that you can ... it's kind of ludicrous. That's why the AAAB works really hard to have cooperative agreements

with CAP and COLA and our competitors. Even though we're competitors, we want to work with you to make sure that you don't have multiple audits going on and the disruption to your patient care. That's why it's really important that we coordinate with your CAP inspection, so we can help you only have one instead of two. It's why we have "deemed status" with CMS, so we can come in and do your federal evaluation for CLIA, so that you don't have the state or the feds coming in. We really try to work with the other regulators.

We work, also, very, very closely with the FDA. I don't think a lot of people realize how closely AABB and the FDA are, other than *physically* they are right down the road. They sit on all of our committees. Our regulatory arm works very closely with them. We try and keep our members informed about what we see, new regs coming down the pike, how you can meet those regs. We work very closely with FDA and, of course, also with CMS and the CLIA arm. Of course, they all have kind of a different view of how they go about doing things. Now, all my transfusion assessors are also trained CAP inspectors. We're able to do CAP inspections for all of our facilities. The majority of our transfusion services are coordinated with CAP. We're doing both of them at the same time. That really does help cut down on the disruption.

Joe: Just to be clear, before we get started looking at the nonconformances that you mentioned as the ones that cross your view point and your desk most commonly; before we do that, you mentioned assessors that work for you. Let me just make sure that everyone is clear. Can you describe the make up, say for example, of an assessment team that goes out to a particular organization?

Anne: I have, on my staff, six lead assessors who are AABB employees. They are trained in, basically, quality systems. They're the experts, even though they have other subject matter expertise. They're trained in quality systems. They head up the teams for all of our accreditations, with the exception of transfusion services and immunohematology reference labs. Those may be done by volunteer assessors. All the rest, they head up the teams. The teams are comprised of subject matter experts, depending on what activities that facility is accredited for. I have my six leads and then I have, at the last count, we had 794 volunteers around the world. Those are in 36 countries around the world. They help us perform the assessments. They're all subject matter experts.

Joe: What we're going to describe today is something that is ... it's kind of based on, and you've given a similar talk to this, I'm assuming pretty much every year, but on an eCast not too long ago ... we're recording this the end of November of 2018, but on an AABB eCast not too long ago, you talked about some of the most common nonconformances you see when facilities are inspected under, at this point, the 31st edition of *Standards for Blood Banks and Transfusion Services*. As you said, the Standards is

based on ... I've done a podcast previously with Pat Ooley about Standards, so I won't go into great detail other than to say, as you mentioned, there are 10 quality system essentials that this particular version of Standards, as well as the other six that you guys have, are centered around, organized around. When you've done this historically, and I've heard you do this more than once, you've talked about kind of a "hit list," if you will, kind of the big things that you've seen...

Anne: It never seems to change!

Joe: ...It's amazing. I would like to kind of go through those. We'll emphasize some more than others. Folks, again, these are all going to be based on things directly out of Standards. I want to start with the one that gets mentioned all the time. I feel like, in some ways, it ends up being, if you'll pardon the expression Anne, a little bit of a “garbage can” in that it is **Standard 1.3: Policies, Processes and Procedures**. I'm just going to read through it real quickly:

"Quality and operational policies, processes and procedures shall be developed and implemented to ensure that the requirements of these [BB/TS] Standards are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed."

Honestly, Anne, when I read that, this seems like ... *why* would people get cited for this? Everyone has policies, processes and procedures. Why is this such a common citation? Why does this one end up being either the number one or close to number one?

Anne: This is probably number one. It's funny because it's number one in every single activity. The most important thing to think about is the very end of what you read. They must be "documented, either in writing or electronically, and must be followed." The amazing thing is, and I know it happened when I was a transfusion manager, you have those few things that you do that you've never documented. When the assessor says, "Well, where is this documented?" It's always, "Oh, because everybody knows that that's what we do." Remember, in God we trust, everyone else needs documents!

The problem is, in this day and age ... you know what? That wasn't a really big deal maybe 15 years ago because people went to a hospital and they stayed until retirement. When these days, when people are... One, you have a workforce shortage, so people are jumping wherever there is a sign on bonus, or it's really hard to find people, or you are back filling with generalists where, in the old days, you would just have blood bank techs, you need to document so that, if you win the lottery and walk out the door, that everybody still can function. It used to be the old days we said if you "got run over by a bus," but I think that's very negative. I think you should go with the lottery.

Joe: Okay [laughs]

Anne: You need to be able to have everything documented so that it can keep going and everybody knows how to do everything, even those things that you swear everybody in the whole place knows how to do. The other thing is, they need to be performed as written. Now, the one time you're going to find out as a transfusion manager that your employees have rewritten your SOP is when the assessor is standing there, because it's happened to me. The assessor says, "I notice you didn't do X."

Joe: [Laughs] Yeah.

Anne: The employee goes, "Oh, no. We don't do steps 2 and 3 anymore. We shortened the process." It's horrible. That's a horrible way to find out that your employees ... because people always make the statement that "there's no creativity in blood bank." That is not true. That is not true. People are very creative. I always say just take your SOP and just watch somebody perform it to make sure that it's really how you have it written.

I think those are the two things. It's the documentation of things that you swear everybody knows how to do. You may have a very creative workforce. Make sure that however you wrote the policy, process, and procedure is honestly as it's actually used in action. That's why this is the most common nonconformance. It's the, "Everybody knows how to do that so we didn't write it down," and then, "Oh, wow. They've created something new," before you even know about it.

Joe: The hilarious thing about what you just said is that, as I was laughing, I was laughing in part because of my pain, because I can tell you, and I know you know this as an assessor and leading your team of assessors, I guarantee you see this all the time, that you can go through that over and over and over with your staff and then, on the day, someone's going to come up with something creative and you're going to go, "*What* is happening right now?!"

Anne: Yeah. "Why did you ever do that?" The poor little thing. Our assessors are also trained in, if you are talking to an employee and you can visibly see that they are very nervous or getting stressed, to walk away and not pursue it because there's nothing worse than somebody who's ... it may be their first time that they've ever been talked to by an assessor. If you can visibly see that you are causing stress, then we just walk away. We train our assessors to do that because the last thing we want to do is interrupt any kind of patient care or make someone feel uncomfortable.

Joe: Sure.

Anne: That's not why we're there.

Joe: Sure. You bet. I have seen that, by the way, in assessors that you and your team have trained. I agree that that happens. That doesn't always happen with other inspecting organizations and I did say “inspecting” there deliberately, so I'll just leave that alone. Thank you. Thank you. Thank you. Okay.

Anne: There you go. I'm so proud of you.

Joe: Wow.

Anne: I'm going to train you before the end, you wait…

Joe: Joe's going to come out of this with training documented. That's fantastic. Okay.

Anne: Oh, that ... but then we have to assess your competency.

Joe: Darn. I could be in trouble.

Anne: Yeah.

Joe: We'll get to that one. The second one I want to mention, and we'll do this one fairly quickly, is **1.4 and that is Emergency Preparedness**. That Standard simply reads:

“The Blood Bank/Transfusion Service shall have emergency operation policies, processes and procedures to respond to the effects of internal and external disasters."

I mention this one, well, not only because you mentioned it in the eCast, but also because we're living in a sad world right now. These things happen way more commonly than we would like. I am certain that ... I'll just speak from personal experience. My blood center is a little over a mile from the Inland Regional Center in San Bernardino, California, where those shootings happened in December 2015. For us, it was pretty stunning how our emergency preparedness was tested so quickly then. Why don't you share with us a little bit, Anne, what you're seeing in terms of where people are struggling with this?

Anne: If you get tired of saying policies, processes, and procedures, just say "PPPs." That's what we do.

Joe: Thank you.

Anne: I think one of the things people miss so often in this Standard, and why we specifically say "external" and "internal," is many facilities have excellent external disaster plans. You brought that to light very well, because it's very sad. We do live in, unfortunately, interesting times. Most people have done an excellent job of doing external preparedness. They are ready for

the mass casualty. They are ready for the hurricane, the flood, the fire. **What we see that people have struggled with is what happens if you have an INTERNAL disaster?** That means, a disaster that is taking place in the transfusion service, blood bank, IRL, so forth that is not affecting the rest of the organization. A pipe breaks in the transfusion service and floods it, but you still have an OR going full strength, labor and delivery still going. You need to support those, but you are in the middle of an internal disaster.

What is your plan? Can you move the blood bank to another area of the hospital? Can you pack up O-negs and go to someplace that you can still support the rest of the hospital? Do you have a sister organization that can take over your function? You need to think about what happens. I know when I first started at my first place of employment after med tech school, we had a fire. The lab burned down. **You need to understand, you need to have processes in place for when YOU are out of commission, but not the whole organization**. People need to really think on that because you need to prepare before that happens because you can't tell the OR, "Well, sorry. We're mopping up the water. We'll get back to you when we're able." You need to think about that internal. That's what people are struggling with.

Joe: Good. Okay. Those are the first two. Let us move onto the third one, which is actually one of the big ones that I want people to be really clear on. That is **2.1.3, which is Competence**.

Anne: See, now everybody just turned off the podcast [laughs]

Joe: I know. For the four of you that are still listening, I hope you stay with us because Anne's got some great stuff to say here. Don't just say, "It's competence. I can't stand it." [Laughs]

Anne: I can't deal with it [laughs].

Joe: *"The evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals."*

This is such a big deal and, as you said, it's met with distaste. People think, "Oh, crud. I don't want to talk about competence." Before we get to the specific things that you guys are seeing, just help us understand, terminology-wise, because for the beginners that are listening: "competence," "proficiency." What do these words mean? What are we talking about with competence?

Anne: Yeah. Now you're using into federal regulation. These are the **Clinical Laboratory Improvement Acts of 1988** that drove all of the federal oversight due to some horrible incidences in hospitals and laboratories. Now, these are not AABB, CAP, Joint Commission, COLA requirements. These are federal requirements. All of us have the same types of

requirements. We interpret them just a little differently, but they are all pulled from the CFR, from the federal regs. Competency, people overthink competency. It's not that big of a thing. Some facilities have gone to the point where they're doing competency and they do patient care whenever they have time, when they're not doing competency. You need to move away from that. **Competency is merely documenting what your employees do in their regular work life.** Think of it that way rather than, "Oh my God. I need this big fancy competency program."

You need to show you train ... So, Sue is a new employee. She gets trained to do ABOs, and then you're going to see if she can perform independently. Basically, you're going to assess her competence to do that test without anybody holding her hand. That is the end of her training. Okay? Now, in the next year of employment, sometime in the next year, you're going to do that again. You're going to assess her competence and you're also, at the end, at annual. And then every year after that, you're going to assess Sue's competence to do ABOs annually. Now, the federal requirement says in the first year there is a "semi-annual" competency assessment. It doesn't say "six months." It doesn't say anything like that. It says "semi-annual." For the AABB, we're looking at sometime between the time that you say, “Sue can act independently” and the first year that you do her competency, you're going to assess in the same to make sure that she's competent to do this job. That's what we mean by semi-annual and annual.

Joe: Anne, I want to make it really clear because I know there's confusion about this. Going back to your illustration, Sue is released, let's just say, on November 30. Before the next November 30, does she have to have her competency for ABO assessed twice or once?

Anne: You have until November to do it, so sometime between the November time period that you said she can work independently, so maybe you're going to do her competence in August for semi-annual and then in November you're going to do her annual competency again. **What confuses people is, at the end of training, you need to assess that she can perform this independently. That is not the "semi-annual competence." That's just the end of training.** That's where people get confused because they're getting confused about the "end of training" is and what "semi-annual" is.

Then, the other caveat with competency in the federal regs is there are six elements that must be assessed for every test that you perform. That gets people all tripped up because you need to have direct observation of the test being performed. You need workload recording or result recording, the testing of a blind sample, direct observation of maintenance of an instrument, and problem solving [*NOTE: You can find a detailed description of the six minimum requirements for competency assessment here*]. Now, the problem is, people look at these six elements and they

start going off on all different tangents. Your employees are doing all of these things in their work life. All you need to do is find a way to document on Sue's record, and it can be a very simple form. Remember, if you're AABB accredited, you have access to the "AABB Commendable Practices Library" [*NOTE: See link at the show page at BBGuy.org/061 for the link to the AABB Member Accreditation Tools*]. Go in there and see if there's a competency form you like and then steal it. That's what it's there for!

Joe: [Laughs] Nice.

Anne: If you watch an employee do a compatibility test, you're going to see them do an ABO, an RH, and antibody detection, perhaps an antibody ID and a compatibility test. You've just ticked off five tests there just by watching them perform a compatibility. Don't think that you have to watch Sue do an ABO on Monday, an Rh on Tuesday, a compatibility test on Thursday. Remember, you can watch an employee just do some of their regular work and tick off the direct observations, then write it down that, "On November 30th, I watched Sue do the following..." Then, for problem solving, if an employee does an antibody panel, that's problem solving. If they solve an ABO discrepancy, that's solving a problem. **Everybody always wants to write a quiz. You don't really need a quiz.** Somebody's going to solve a problem sometime during the year that they work. So, write it down on their form. The blind sample, if your people do PT, write down, "On the November 30th, Sue did a PT." If you don't have enough PT for all of your employees, use a blind sample for them to do an unknown.

The one that's really tripping people up is the direct observation of instrument maintenance, because now we're starting to move into the era when BioMed takes care of all your instruments or the vendor comes in because they're all computerized. If your employee does not do maintenance on any instrument or function checks on any instrument because they're no longer done within your facility in that manner, so BioMed comes and does everything, you need to document on that employee's competency that they do not have that requirement in their employment. It needs to be documented on that...you can't just make a blanket statement that, "None of my people do instrument maintenance." You need to put it on that employee's competency record. That's perfectly acceptable because a lot of people don't do those things anymore.

The idea is don't think of competency as this huge program that you put into place and it's really fancy and intricate. It's just one piece of paper where you're recording what Sue did over the course of her work life for one year. That's her annual competency. ***The problem is, people make competency so complicated that there's no way they can actually DO the competency program they put in place. So, simple, simple, simple!***

Joe: Well, Anne, there's a whole lot more that we could say about that but we gotta move on. We've talked about "PPP (Policies, Processes, Procedures)", Emergency Preparedness, and then spent some time doing Competency. The next one, I'm going to roll some things from section 3 of the QSEs, which is Equipment issues, kind of into one, if you don't mind. It starts with **3.5, which is Equipment Monitoring and Maintenance**, and then branches out into some other stuff. The short version of this is that 3.5 says:

"The Blood Bank/Transfusion Service shall have a process for scheduled monitoring and maintenance of equipment that, at a minimum, is in accordance with manufacturer's written instructions."

I know a couple of the places where you see this is **3.7.1, which is Alarm Systems**, and **3.8, which is Warming Devices**. Why don't you just tell us a little bit about some examples of things that you see as examples of nonconformances with these standards?

Anne: Okay. One thing that you said that's really, really important is "manufacturer's written instructions." The *AABB Standards* require you to follow the manufacturer's written instructions. One thing I want everyone to remember is that the AABB Technical Manual is a fabulous reference book put out by AABB Press. It is not Standards, regulation; It is the editor's opinion. Basing your equipment preventive maintenance on the Technical Manual could get you into trouble. Look at your manufacturer's written instructions for that. The other thing is, just ... because you've set things for a really long time, be careful that your manufacturers aren't getting all crazy on you, because when you get reagents, RhoGAM kits, anything coming in, double-check the storage requirements because if you have a fridge where you keep your blood and you also keep your RhoGAM in there, your blood is at 1-6C. Then, if you look on your RhoGAM package, it may be 2-8C. If you have your alarm set at 1.5C, by the time the alarm sounds you've lost your RhoGAM. You need to set that alarm at 2.5C.

Just remember that wherever you are storing, you need to make sure that your alarms apply to everything in that fridge and, remember that you are always following the manufacturer's written instructions. You can be more stringent than the manufacturer's written instructions, but you have to follow what they say. Those are the two things that people sometimes struggle with.

Joe: I can't leave this one without talking about warming devices because, I have to tell you, people send me emails sometimes just because of what I do with this podcast. I have received many emails from people that've gotten nonconformances regarding blood warmers saying, "*That's not fair!* How..."

Anne: "We don't have anything to do with those!"

Joe: Exactly!

Anne: "BioMed takes care of them and nursing uses them and they don't belong to us!"

Joe: Yes!

Anne: Okay. The way to remember this is, the ***AABB Standards*** **go from vein-to-vein, so the vein of the donor to the vein of the patient**. **Anything in that window that touches the blood comes under the purview of the medical director of that service**. If your used blood warmers, there needs to be some way for BioMed to share with you the maintenance and that things are being done correctly. I don't have any problem with BioMed taking care of them and nursing using them, but remember, the blood touches them. Anything the blood touches is under the overview of the medical director. You need to have review of the preventive maintenance and how they are used. Those things that ... Everybody always forgets the blood warmers because you never see them. You just know they're floating around somewhere out there.

Joe: Honestly, for those of you that are listening, especially if you're just starting out or if you're in a facility where you're going, "Huh. I wonder, do we use blood warmers here?" You probably do and you probably need to check them out, for sure.

Anne: Yeah. You don't want the assessor to be the one to find your blood warmers.

Joe: Exactly. Worm yourself into that little process there, folks, and you'll be glad that you did the next time your AABB assessor comes along. Anne, let's move on and let's talk about another big one. I know this is one that's big on your radar. It's something that's kind of near and dear to my heart, too. That's **5.1.1, which is Change Control**. This one seems like, again, another obvious one to blood bankers because we're careful people in general. The Standard reads:

"The Blood Bank/Transfusion Service shall have a process to develop new processes and procedures or change existing ones."

I'm not going to read the whole standard, but that's the heart of it. Let me ask you, is the issue that we don't HAVE change control, or that the change control that we have just isn't effective?

Anne: Well, sometimes people, again, the whole, "There's no creativity in blood bank," that's not true. Sometimes, the change control process is so creative and so intricate that there's no way you'd ever have that many people sign off on that many things in that many ways. Make sure that you have a very straightforward easy way to show the assessor how you put change into being. If you send an email out telling people to review

something, how do you know everybody has gotten the email and everybody has reviewed that? You need to close the loop. You can't just say, "Oh, we send everyone an email." Okay, so how do you know that it was opened, read, and so forth? Don't get really creative with the way it's done, just really straightforward and easy change control.

The other thing people struggle with is you have a new process or procedure, you validate it, you train everyone how to do it, then you start doing it. And THEN, the medical director signs off. You need to move that back. You can't start training and implementation until the medical director has looked over the entire validation and approved it. **Remember the sequence of events: The validation, THEN the sign off and acceptance by the medical director, THEN you train, THEN you implement**. **That's one of the most common things we see is the date of implementation is before the medical director signs off.** A lot of times, it's because when we arrive today, the medical director miraculously signs off on things that happened like yesterday, like every SOP was reviewed yesterday. Yeah. We kind of notice those things [laughs]. Yeah. Pick a date. Just make it up-

Joe: Noooo.

Anne: You know. Yeah. Remember that order, that order. Sign off, then training, then implementation, but you can't start even the training piece until he or she signs off and says, "Run with it."

Joe: There's, again, a lot of detail to that and a lot of things that we could talk about in terms of change control, but I think we should just leave it there and move on to talk about another one that does trip people up sometimes and has some particularly scary consequences. I want to quickly mention proficiency testing. Obviously, everyone is well familiar with the fact that we have to do proficiency testing. The **Standard 5.1.2** specifically says:

"You have to participate in a proficiency testing program, if available, for testing regulated by CLIA and performed by the facility."

Again, Anne, what kind of things are you seeing as nonconformances for proficiency testing? In particular, can we talk about the whole "treat the samples the same way as patient samples" thing?

Anne: Right. Now you're back into the feds and the federal requirements for proficiency testing. You need to make sure that your proficiency testing sample is being treated the same way you would treat a patient. The supervisor can't do all the PT. You can't do it three times and pick the best answer. You need to treat it exactly like you treat a patient. It should be done on all shifts at all times. You need to rotate it among all your shifts, so don't get creative and give it to that one tech you know is going to do it perfect. It needs to be rotated, just like a patient.

However, this is where we get into the “you treat it like a patient but not.” **If you test a sample to a certain point and then you send it someplace else, for either confirmatory testing or further testing, you can't do that with a PT if you're sending it to somebody else with a different CLIA number**. If I have a BACT/ALERT in my donor center and I inoculate the bottles and then I send my positives to the microbiology lab within my facility that has the same CLIA number, that's fine. If I take my BACT/ALERT positive bottles and send them to a reference lab that is a *different* CLIA number, I can't do that with PT because that's called "PT referral." That's a huge no-no under federal regs. Your medical director is going to be prohibited from heading a laboratory for a number of years. It has extreme consequences.

We did work very hard with the federal government to put in some stipulations on inadvertent referral. They have been a little nicer about that. Your medical director only loses his license for like two years instead of five, because it's the feds. Remember, you need to know where that line is. If you take a sample and you do everything, so you get comprehensive transfusion sample and in your facility you do the whole thing, you do antibody ID, you do anything that's required, then you just take it to completion. If you do only ABO/Rh and antibody screens, and you send your positive antibody screens out for identification, you need to stop your PT at that point. The PT has to stop at the point where it leaves to go to another CLIA number.

Joe: I often tell people in my blood center that part of their job is to keep Dr. Chaffin out of jail...

Anne: Yes. That's always nice!

Joe: It's always a good thing. This one, obviously, is not necessarily a "jail thing." I tell them, "Please allow me to continue to work. That would be a good thing."

Anne: Yes.

Joe: "So, let's not share those samples." Yes. Okay, let's move onto **5.1.3, which is Quality Control**. Quality Control, again, 5.1.3 seems pretty obvious:

"A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods perform as expected."

Everybody does QC. How could people be struggling with any of this, Anne?

Anne: It's kind of how you *handle* QC. When you have QC that fails, you need to have an entire process to close the loop. You have to make sure that your

QC is complete. When you have QC that doesn't meet expectations, you need to make sure you're following the manufacturer's written instructions for the reagent that you're using as far as QC. Make sure they haven't changed that package insert since last you read it. Those are the common things that we see. It's that failure to close the loop.

One thing I want to talk to people about are "ditto marks" and lines drawn through on QC records. You can't do that, because the Standard in the AABB is that you record all results "concurrent." Ditto marks and a line all the way down a QC form is against the Standards because you can't say, "I did that all at one time." Be careful of your ditto marks. If you have a QC record that has one column that is always blank because you don't use it anymore, revise that form. We don't want to see anything blank.

Joe: That's really, really helpful. The next one, which is 5.1.4, kind of goes with that a little bit, but actually more goes with something that you talked about before in your example of Rh immune globulin and perhaps the alarms not being set properly. This is **5.1.4, which specifically talks about Use of Materials,** and it says that:

"All materials shall be stored and used in accordance with the manufacturer's written instructions."

I'm assuming that that's the kind of thing that you're talking about. Your assessor's looking around and they find something that's supposed to be stored at such and such temperature or, for such and such time and it's out of that range. Is that what we're thinking about here?

Anne: Exactly and also, following the manufacturer's instructions. Remember to really look at those new package inserts when they come in. You'd be surprised how often manufacturers actually change things in not only QC but also sometimes in storage, number of drops you use, and so forth. Just remember to give those a good look-see when they come in and make sure, because the assessor's going to be opening that, looking, and watching you do something. You don't want to find out at that point that it's now one drop instead of two drops. I think what you do is you have ... For instance, you get a new antisera and it comes in with a new package insert. Give that package insert to your newest employee and have them review it versus the SOP. I know if I've been doing something for donkey's years *[NOTE: Anne STILL means, "for a really long time!"]* and I read the package insert, I'm going to read it exactly like I remember doing it all the time. Put a new set of eyes on it.

Same thing is taking the assessment tool that's available to all of our accredited facilities, divide it up in your employees and say, "Hey, you do the equipment area." Have them work through what a Standard looks like, what the assessor may be looking for, and figure out where it's found in your lab. One, it takes away the stress of an assessment because they get

used to how Standards are worded, which is very difficult, especially for new employees because *AABB Standards* are written as goals. They're not prescriptive. We're not going to tell you to do something in a prescriptive way. We need you to figure out how to do it in your own facility, because a rural hospital in Alaska with four beds is different than a university hospital in the middle of Philly.

Joe: I think that's really, really helpful. Let us finish with something that, I gotta be honest, just puts me to sleep. If we haven't lost everybody before now, this last one, **6.0, Documents and Records**, oh boy. With that intro, how can anyone resist listening to what we're about to say?

Anne: I know! This is a hot topic.

Joe: This is a hot topic. Okay. Again, we're blood bankers and we certainly know that we have to have PPP to ensure that documents are identified, reviewed, approved, retained, et cetera, et cetera, et cetera. Some of the examples that you've given as places where people should focus include a master list of documents, the review and approval of those documents every two years, and use of only current and valid documents. I'll open the floor to you, Anne. What kinds of things are you guys looking for and what are you seeing as the places that people struggle with those issues?

Anne: Well, I think the one thing you have to make sure of is that you have a handle on all of the documents that are being used in your lab. You know everybody always has the employee that has all those printed out SOPs squirreled away in their lab coat pocket. Be aware of those employees and make sure that they have the RIGHT SOPs squirreled away in their lab coat pockets. If you have a job aid posted, if it is a controlled job aid, we want to see it on your master list and to see the edition. If it is an uncontrolled job aid that you are using because you just started doing something new, kind of gel testing or something, stamp it as an "uncontrolled copy" so the assessor can clearly see that it is not part of your document control. It is being used as an uncontrolled job aid.

Make sure that your policies, processes, and procedures are reviewed every two years, FOR REAL, not the day before we arrive, and it's all in the same blue ink. Remember, we really honestly want the executive management to be participating in the life of the lab. One of the ways to participate is that review. You also, at this point, go back into the federal regs when it comes to review of documents. **Any major revisions or changes, new SOPs, or revisions to any process, policy, or procedure that has to do with CLIA testing must be signed off by the person whose name is on your CLIA certificate**. CMS does not define what a "change" is. It's up to you to tell the assessor what you consider to be a "major change." Then we expect the person on the CLIA certificate to be the signer of those.

Now, a lot of times you have a very large institution. The CLIA director is the guy down the hall who heads up the whole lab. He wouldn't know Transfusion Medicine if he was the last guy on earth. He's a chemist or an Anatomic Path[ologist]. It's okay for the transfusion director to then do a second review, but the first review of any new PPP that has to do with CLIA testing or major change that you define, we want to see HIS signature, the guy down the hall, on it first. He cannot delegate that to somebody else. That's not a delegatable thing. He needs to be the one who signs off first. We've had some of our large institutions actually have their transfusion service get their own CLIA number and move away from that because they feel that that helps them. That's always a possibility.

The AABB doesn't have any problem with you having a signature page at the front of an SOP book, just that your document control policy explains to the assessor how that is used. Same thing with if you have references and you say "Current addition of Standards," "Current edition of Technical Manual;" that is perfectly acceptable as long as you can show me the process you have to review new Standards and new references. You can use that. Usually that's much easier than saying "31st edition," because the Standards change every two years. If you really want to redo it every two years, that's fine, but "current edition" is fine. You need to put in your document control how you review all the new additions of your references. That's perfectly acceptable.

Again, keep it simple. **Don't make it complicated, especially with some of the new electronic software that's out there for people to keep their documents. Don't get really fancy. Keep it simple so that you can keep on top of it, because those things can get away from you really, really fast if you make it too complicated. That's my whole talk: Keep everything simple!** [Laughs]

Joe: No, you're absolutely right. Anne, this has been really remarkable. Before I let you go, I want to make mention to people, make sure people are aware, in your eCast you gave some resources and places that people can go to find more information, get supporting documentation. You mentioned assessment tools and the Commendable Practices Library. I'm going to put information about that on the show page for this episode, everyone, which will be BBGuy.org/061. You'll have all that available. Anne, the last thing I would like for you to cover is, if you're working, say for example, at an AABB-accredited facility and you're implementing a new process and you want to make sure that it meets the expectations that your assessors are going to have when they come in, is there something that you can do? Is there a contact? What can they do?

Anne: Absolutely. You can contact [us]. If you want to do email, do accreditation@aabb.org. If we can't answer it directly, if it has to do with the intent of the standard, we'll get Christopher and his crew to weigh in. If it's accreditation, please, accreditation@aabb.org. We absolutely love to

hear from y'all. We also have the phone. That would be 301-215-6492. Everyone in my department is a med tech, either in Transfusion Medicine, cellular therapy, et cetera. We are always delighted to speak to other laboratory professionals about what's going on and how we can help. Make sure that you use the AABB website, especially if you're looking for regulatory information, because we can translate FDA guidance into real-life language. If you ever have any concerns, problems, issues, you just want to run something by someone, just give us a call.

Joe: Well, Anne, it has been my incredible honor and joy to have you on the podcast. You've been a blast and so helpful. Thank you so much for being here!

Anne: Oh, super! I loved it! There's nothing I like more than talking about AABB and how we can help, because we are there for our members and delighted to have had the chance to just talk a little bit about the program and to encourage people to contact us so we can help in any way at all.

Joe: Thanks, Anne. You're the best. Take care.

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Joe: My thanks, once again, to Anne Chenoweth for joining me today. I have a pretty strong feeling that those of you who are responsible for AABB accreditation might listen to that one more than once. Anne just gave us a ton of practical tips that can really make every facility better, again, whether you are accredited by AABB or not.

Remember, you can go to wileyhealthlearning.com/transfusionnews and get your hour of totally free continuing education credit for both doctors and laboratorians. Also, you can go to the show page for this episode, which is BBGuy.org/061 to find the transcript and some AABB webpage references as well.

One quick note, this episode is being released in mid-December 2018. If you are a pathologist and you plan to use this episode for your Continuing Certification credit with the American Board of Pathology for this year, for 2018, then you need to complete that paperwork at wileyhealthlearning.com/transfusionnews for this or really any other CE episode before December 28 of this year, so before December 28, 2018. You can still get credit after that date, but it won't be for 2018, so again, specifically for 2018, finish it before December 28.

I am planning to release one more episode of Blood Bank Guy Essentials before the end of 2018, so please check back soon, but until I see you again, as always, I hope that you smile, and have fun, and above all, please, never, EVER stop learning! Thank you so much for being here. I'll catch you next time on the Blood Bank Guy Essentials Podcast.